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Food and Nutrition Service

Special Supplemental Food Program for Women, Infants and Children; Proposed Changes

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

Special Supplemental Food Program for Women, Infants and Children

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This notice proposes various changes in requirements for the Special Supplemental Food Program for Women, Infants and Children (WIC Program), in order to comply with Section 3 of Pub. L. 95–627 which amends Section 17 of the Child Nutrition Act of 1966 and extends the authorization for the WIC Program through FY 1982. This proposal deals with the kinds and quantities of supplemental foods provided under the WIC Program.

DATES: To be assured of consideration comments must be received on or before January 28, 1980.

ADDRESS: Send comments to Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Jane McNeil, Acting Director, Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447–8206.

SUPPLEMENTARY INFORMATION: Pub. L. 94–105 specified key nutrients which were to be provided by WIC Program supplemental foods. New WIC Program legislation enacted by Pub. L. 95–627 requires the Secretary to design food packages to contain nutrients which, based on the latest nutritional research, are shown to be lacking in the diets of the WIC Program target population. The Secretary is required to ensure to the degree possible that the fat, sugar and salt content of the prescribed foods is appropriate. State agencies may request substitutions in the WIC food packages to allow for different cultural eating patterns. The substitution must provide as nearly as possible the nutritional equivalent of the target nutrients offered through the supplemental food which is replaced, and the substitution must be approved by FNS. Pub. L. 95–627 allows the Secretary to donate commodities at a State agency's request for use in the Program.

These requirements are proposed to become effective 6 months after final publication to allow State agencies that period of time to phase these changes into their food delivery systems. These proposals will ensure that the food packages are closely aligned to participants' needs for supplemental foods, will encourage breastfeeding and will result in improved services to WIC participants. As required by Executive Order 12004 and Department regulations, a draft Impact Analysis Statement concerning the major proposals is available from the address listed above.

The Department believes that public participation in policy development serves as a valuable information source for developing and assessing program alternatives. The Department further believes that any program which it administers should reflect the needs and viewpoints of the public served by the program. Because public participation serves as a means of improving the effectiveness of the Department programs, public input is particularly important prior to the development of regulations. Consequently, prior to issuing this proposal the Department actively sought the advice and assistance of knowledgeable individuals, groups and organizations which were willing to offer assistance and expertise in developing regulations that would most effectively satisfy the health and nutritional needs of the eligible population. The following steps were taken in the development of this proposal.

National Advisory Council on Maternal, Infant and Fetal Nutrition

Input on the WIC food packages has been periodically received from the Advisory Council established by Pub. L. 94–105. The members of the Council have widely diversified backgrounds. The membership includes State and local health officials and administrators of the WIC and Commodity Supplemental Food (CSF) Programs, representatives of the Department of Health, Education and Welfare, three parent participants in the programs, a pediatrician, an obstetrician, representatives from migrant farmworker and advocacy organizations, and a person involved in the retail sale of foods used in the Program. This council has the ability and expertise to consider all aspects of the food packages and is extremely helpful in providing insight into how the food packages are viewed by persons involved with the Program.

The council biennially submits a written report to the Congress and the President with recommendations for administrative and legislative changes. Advisory Council meetings were held in June 1977; February 1978; June 1978; February 1979; May 1979; and September 1979. Prior to each meeting a notice was published in the **Federal Register** announcing the dates of each meeting and advising that the meetings were open to the public. At these meetings the nutritional needs of the target population and the specific WIC food packages were discussed.

Public Hearings. In June 1977 public hearings were held in seven cities to consider comments regarding possible legislative and regulatory changes for the WIC Program. The hearings were held to solicit public testimony concerning the future structure and administration of the Program. The Washington Supplemental Food Programs Division, the Regional Administrators and their staffs, and the Information Division worked together to ensure that all interested parties were aware of the hearings and were encouraged to attend and testify. The Supplemental Food Programs Division published a notice in the **Federal Register** and worked with the Information Division to produce a public release, posters, and other forms of communication to bring media attention to the hearings. In addition, the supplemental Food Programs Division sent over 750 invitations to individuals as well as to every Governor, the House Education and Labor Committee, the Senate Select Committee on Nutrition, all members of the Advisory Council and Advisory Committee on Nutrition Evaluation, advocacy groups, grass roots organizations, industry representatives and professional groups. Regional Administrators wrote to all State Chief Health Officers and to all State WIC Coordinators. All individuals who desired to testify were allowed to do so. Time was allowed at the end of each speaker's testimony for questions from the floor. Public testimony on the food package covered the addition of new food items, the sugar levels of WIC cereal, the variety of cereals available, and the allowance of non-iron fortified infant formula.

Advisory Panel Meeting. The Department convened a Food Package Avisory Panel in October 1978 to review the current WIC Food packages and recommend changes. Members of the Advisory Panel included State health officials, representatives from the nutrition community and advocacy groups and a parent participant.

Public Comment. The preamble to the final WIC regulations published on August 26, 1977, included a discussion of the WIC authorized cereals. Specifically, the sugar and fortification levels of the cereals, the iron requirement for the cereals, and the issues of whole grains and artificial flavors and colors were

included. The Department requested the public to comment on these issues and as a result received 300 comments. The Department thoroughly analyzed all of the comments and considered them in developing this proposal. The comments are discussed below in the applicable sections of the preamble.

Other Meetings. As another means of obtaining public input, Supplemental Food Programs Division personnel attended several regional, State, and local meetings to hear and relay public opinions concerning possible changes in the food packages.

Although the above mentioned steps were taken to develop this proposal, the Department considers the 60 day comment period essential to the development of final regulations. The public is invited to submit written comments in favor of or in objection to the proposed regulations or to make recommendations for alternatives not considered in the proposed regulations. Comments should cite the appropriate section of the regulations, include a rationale and, whenever possible, provide supportive data. To be assured of consideration all comments should be received or postmarked by the specified deadline. Copies of all written comments received pursuant to this notice will be made available for public inspection during regular business hours (8:30 a.m. to 5:00 p.m.) in Room 4405, Auditors Building, 201 14th Street, S.W., Washington, D.C. 20250. The Department will give careful consideration to all comments before final regulations are published.

General Discussion

The current food packages are designed to provide foods containing the nutrients specified in Pub. L. 94–105, which are protein, iron, calcium, vitamin A and vitamin C. These nutrients were chosen based on studies which suggested that they were lacking in the diets of the WIC Program target population. The authorized supplemental foods are iron fortified infant formula, infant cereal, milk, cheese, eggs, iron-fortified breakfast cereal and fruit or vegetable juice which contains vitamin C.

As mentioned earlier, Pub. L. 95–627, which extends the WIC Program, defined supplemental foods as those foods containing nutrients determined by nutritional research to be lacking in the diets of the target population. The Department believes that research in this area has demonstrated that many of those nutrients specified in Pub. L. 94–105 may still be lacking in the diet of the WIC Program target population. Additionally, research has not provided evidence of changes in the dietary habits or economic situations of the target population sufficient to warrant changing the nutrients specified in the WIC food packages. Therefore, the nutrients protein, iron, calcium, vitamin A and vitamin C will continue to be provided by the supplemental foods authorized under the Program.

There has been considerable discussion about the meaning of the term "supplemental" as it relates to the WIC Program. A number of questions have been raised concerning the levels of nutrients the food packages should provide. The Department believes that the food packages should not be expected to meet all the nutritional needs of participants, but that the foods provided should be used in addition to a variety of other foods. However, the Department acknowledges that participants have limited incomes; therefore, it may be unrealistic to expect participants to purchase sufficient food to provide adequate amounts of all nutrients, particularly the specific nutrients provided in the WIC food packages. While nutrition education is a vital part of the Program and should emphasize the need for a varied diet, nutrition education cannot compensate for insufficient income. Therefore, the Department believes that the food packages should provide high percentages of the Recommended Dietary Allowances (RDA) for protein, iron, calcium, vitamin A and vitamin C.

The Department believes that research has indicated a need for increased amounts of folic acid and zinc in the diets of the WIC Program target population and a trend away from consumption of fiber containing foods in the general population. Therefore, folic acid, zinc and fiber were considered when developing the proposed food packages.

Dietary intake information suggests inadequate intakes of folic acid in relation to the RDA for the U.S. population as a whole, (*1*) and for pregnant adolescents in particular. (*2*) However, dietary intake data must be interpreted with caution because of the unavailability of reliable tables of the folic acid content of foods. Biochemical and clinical meaures may provide a more accurate profile of nutritional status with regard to folic acid. Information from the *Ten-State Nutrition Survey* on serum and red cell folate in various population groups in the U.S. indicates that non-Caucasians and low-income individuals in particular are at risk for folic acid deficiency. (*3*) Folic acid deficiency is difficult to diagnose clinically. However, megaloblastic anemia resulting from folic acid deficiency may be observed in 2.5–5.0 percent of pregnant women attending hospital clinics in developed countries. (*4*) Since megaloblastic anemia is the most advance state of prolonged folic acid deficiency, these findings are indicative of a higher incidence of marginal deficiency. Regardless of the shortcomings inherent in each of these direct assessments of the folic acid status of the WIC Program target population, it has been clearly demonstrated that pregnancy and lactation impose a significant nutritional stress on the mother which leads to an increased requirement for folic acid. (*5*)

Recent evidence suggests that marginal states of zinc nutrition exist in segments of the U.S. population. (*6*) The incidence in Americans of three zinc-responsive syndromes alerted researchers to the possibility of marginal zinc status in a significant portion of the population. Findings utilizing dietary analyses and estimated availability of zinc suggest that some infants, some pregnant women and some living on low-income diets have a marginal to deficient intake of zinc. (*7*) In a recent study, a group of apparently health, low-income preschool children in Denver were found to have a high incidence of suboptimal zinc nutrition with consequent zinc depletion. (*8*)

Compared to diets of other populations, the American diet may be low in fiber content. Despite an increasing interest in a possible protective role of fiber in various diseases prevalent in the U.S., the consumption of total crude fiber has not increased in the last twenty years. Crude fiber intake dropped by 28 percent from 6.8g/day in 1909 to 4.9g/day in 1957 to 1959 and has remained at that low level until the present. (*9*) Problems in the definition and analysis of fiber, and the lack of standards for recommended intakes, make it difficult to assess fiber intake in relation to the needs of the WIC Program target population.

The Department believes that sources of zinc, folic acid and fiber should also be provided by the food packages. However, considerations of cost and therefore of the potential number of persons served through the Program, and administrative feasibility prevented the inclusion of additional foods high in zinc and folic acid. Therefore, the Department is proposing to include foods that contribute to dietary zinc and folic acid intake, but at a level lower than the other specified nutrients. The addition of dried beans or peas or peanut butter makes a contribution to

the zinc level of the food packages for pregnant and breastfeeding women and children. Orange juice is an excellent source of folic acid and may be selected as the juice component by all women, children and infants 6–12 months of age. The Department is requesting comments on the possible inclusion of whole wheat bread, which contains fiber, in the packages for pregnant and breastfeeding women and children.

Because of associations that have been made between the overconsumption of sugar, fat, and salt and certain public health problems, Congress has expressed the desire that the sugar, fat, and salt content of the foods prescribed in the WIC food packages be appropriate. The Department is proposing to moderate sugar levels by establishing a maximum sugar content for authorized cereals. The sugar content of the proposed food packages is discussed in detail in the section of the preamble that pertains to cereals.

Consideration has also been given to the fat and the salt content of the food packages. Recommendations for the reduction of fat and salt in the diet have been made for the general population and the Department recommends that nutrition education efforts in the WIC Program stress the importance of consuming appropriate amounts of fat and salt. The levels of fat contained in the WIC food packages will vary considerably depending on the participant's choice of foods. For example, if the participant chooses foods that are highest in fat from among all the foods offered for pregnant and breastfeeding women, approximately 59 percent of the calories provided by the package would come from fat. However, if low fat foods, such as skim milk, were chosen, the package would provide only about 11 percent of the calories from fat. Therefore, there is a wide range in the fat as percent of calories in the food packages. The Department acknowledges that the upper end of this range may be high. However, it is important to recognize that the food package is a supplement to the diet. Therefore, the percentage of fat in the food package is not representative of the percentage of fat in the total diet. In fact, the food packages can be expected to provide a greater percentage of fat because a large proportion of the calories in the food packages are derived from foods with a potentially high fat content, such as milk and cheese, which are included because they also provide high quality protein and calcium, nutrients that are needed by the target population. It is expected that with nutrition education participants will not select foods from the food packages which provide the highest percent of calories from fat. Furthermore, it is expected that the other foods in the participants' diets will not provide such a large proportion of calories from fat. Therefore, the percentage of fat in the total diet, even for those who select foods with relatively higher fat contents, will be less than 35 percent, the level recommended by the American Heart Association and National Academy of Sciences. (*10*) The Department also recognizes that individuals have different dietary needs. The design of the food packages allows for individual tailoring so that the levels of fat in the packages can be controlled.

A wide range also applies to sodium values. The food package for children could provide from 438 to 2241 mg. of sodium per day and the food package for pregnant and breastfeeding women could provide from 502 to 2525 mg. of sodium per day. The Estimated Safe and Adequate Daily Dietary Intake of sodium, determined by the Food and Nutrition Board of the National Academy of Sciences, is 325–975 mg. for children 1–3 years of age and 450–1350 mg. for children 4–6 years of age. The Food and Nutrition Board does not specify Estimated Safe and Adequate Daily Intakes of sodium for pregnant and Breastfeeding women. However, the Estimated Safe and Adequate Daily Dietary Intake of sodium is 900 mg.–2700 mg. for adolescents and 1100 mg.–3300 mg. for adults. (*11*)

The lower value of the sodium range for the children's food package lies well within the range determined by the Food and Nutrition Board for children 1–3 years of age, and below the minimum intake for children 4–6 years of age. The Department acknowledges that the upper value of the sodium range for the children's food package may be high. However, over 75 percent of the sodium for this calculation was obtained from the use of a high sodium cheese for the milk component of the package. Similarly, when low sodium foods are chosen, the milk component, whole fluid milk, contributes over 85 percent of the total sodium in the package. The Department believes that the contribution of high quality protein and calcium made by milk and cheese justifies their inclusion in the children's food package despite their sodium levels. The sodium levels of the food package for pregnant and breastfeeding women are comparatively lower. The upper value of the range falls within the Food and Nutrition Board guidelines. Milk and cheese are also the major sodium contributors in this package and the same rationale for their inclusion applies.

In designing the current food package, the Department grouped participant populations which consume the same general categories of foods with the intent that a competent professional authority at the local agency would tailor the food packages to meet the nutritional needs of individual participants, and language to that effect was included in the regulations. Three food packages are currently specified for participants; one for infants, one for women and children and one for children with special dietary needs. However, available information, including a recent GAO report, indicates that food packages frequently are not tailored. (*12*) Lack of adjustment of the packages has resulted in criticism that the Program promotes overfeeding and encourages waste. The regulation on food packages set forth in this proposal alters this pattern.

This proposal delineates additional food packages in an effort to respond to criticism that the current three food packages provide too much food in relation to the nutritional needs of certain categories of participants. The proposed packages still provide considerable flexibility and the Department continues to encourage the competent professional authority to tailor the food packages to suit individuals' nutritional needs.

The Department is proposing seven different food packages rather than the current three. These food packages are designed to more accurately reflect infants' nutritional and developmental needs and pediatricians' corresponding feeding recommendations, to reflect the additional nutritional requirements of pregnant and breastfeeding women, and to correspond more closely to the recommended eating patterns for preschool children. The food packages are defined for categories of participants as follows:

1. Infants 0 to 2–4 months.
2. Infants 2–4 to 6 months.
3. Infants 6 to 12 months.
4. Children 1 to 5 years.
5. Children 1 to 5 years with special dietary needs.
6. Pregnant and breastfeeding women.
7. Non-breastfeeding postpartum women.

Infant Packages

This proposal contains a number of changes in the infant food package. There are three food packages proposed for infants which provide a general timetable for the introduction of authorized foods into the infants' diets.

Infant Formula. The Department has received many comments from health professionals and participants requesting the authorization of non-iron-fortified infant formula for infants who do not appear to be able to tolerate iron-fortified infant formula. The Department has thoroughly considered these requests and is concerned about the impact allowing non-iron-fortified infant formula would have on the WIC Program. Iron deficiency is one of the most prevalent nutritional problems of infants and young children in the U.S. Although infants are born with iron stores accumlated in utero, which are protective during the first few months of life, inadequate intake or iron during infancy may lead to the depletion of these stores and iron deficiency.

Intolerance to iron-fortified infant formula is a controversial issue. Although some physicians are opposed to the use of iron-fortified formula because of the belief that it causes fussiness, colic, spitting up, diarrhea or constipation, other physicians use iron-fortified formula regularly and consider such manifestations uncommon. (*13*) The Department is concerned that if a physician believes an infant manifests signs of intolerance to iron-fortified infant formula and places the infant on a non-iron-fortified infant formula, the infant will not be able to receive any infant formula through the WIC Program unless non-iron-fortifed infant formula is authorized. The Food Package Advisory Panel also expressed this concern in making its recommendation to allow non-iron-fortified infant formula when it is prescribed by a physician and concurrence is received from a State health official. However, because of the controversy concerning intolerance to iron-fortified infant formula, the Department believes additional public input is needed to make a decision. Therefore, the Department requests comments from health professionals on whether non-iron-fortified infant formula should be authorized for use in the WIC Program. Comments will be used in making a final decision which will be published in the final regulation.

In order to better meet the needs of some infants and some children with special dietary needs who consume greater quantities of the infant formula than currently authorized, the Department is proposing that an additional 52 ounces of concentrated liquid infant formula (or its equivalent in powder or ready-to-feed as set forth in the proposal) be allowed in the three infant food packages and the food package for children with special dietary needs when a physician determines and documents the need for the additional formula. The authorization of additional infant formula should be of assistance when concentrated liquid infant formulas packaged in 14 ounce cans are used. Currently twenty-eight 14 ounce cans of concentrated liquid infant formula can be provided to participants. With the authorization of the additional formula, participants will be able to receive thirty-two 14 ounce cans when a physician determines and documents the need for the additional formula.

Cereal. Current recommendations for infant feeding practices recommend the provision of only breast milk or infant formula to infants during the first months of life. In designing the proposed food packages, the Department gave consideration to these recommendations and the recommendation of the Food Package Advisory Panel to delay the introduction of solid foods to 2–4 months of age. The use of an age range would allow flexibility to accommodate individual differences in growth and development. Therefore, the Department proposes that infant cereal not be provided in the infant food packages until 2–4 months of age.

The Department has received many requests to allow older infants to receive adult cereals. The reason most often stated is that older infants prefer the texture of adult cereals and often refuse to eat the infant cereals. The Food Package Advisory Panel supported this request. In reviewing this option, the Department consulted several pediatricians who raised serious concerns about such a change. The critical time for the development of anemia in infancy is after body stores of iron built up in utero are depleted, which generally occurs after 4–6 months of life in term infants. (*14*) The infant must, therefore, rely on a good source of dietary iron. The cereal issue would be a lesser concern if infants were still receiving iron-fortified infant formula. However, there are data to indicate that a significant number of infants are no longer fed infant formula by 9 months of age but are fed milk. (*15*) The iron used in infant cereals is electrolytically reduced iron of small particle size. (*16*) Adult cereals however, may vary as to the iron compound used for fortification, and, therefore, in the bioavailability of that iron. (See the section of the preamble of Bioavailability of Iron.) In addition, infant cereals contain more iron than that available in cereal fortified at 25 percent of the USRDA for adults and children four or more years of age which is proposed for inclusion in the packages of women and children who do not exhibit signs of iron deficiency. Therefore, in order to maintain an infant package providing an optimum level of specified nutrients, the Department is proposing that the current requirement that only infant cereals be provided to infants be maintained.

Juice. Current regulations authorize juice for all infants 0 to 12 months of age. This regulation proposes that juice not be authorized for infants until 6 months of age. This proposal was based on consideration of a joint recommendation by the American Academy of Pediatrics and American Academy of Pediodontics which discourages the feeding of juice from a bottle rather than a cup, (*17*) and on consideration of the vitamin C content of the food packages. Infant formula contains considerable amounts of vitamin C, whereas milk contains only minimal amounts of vitamin C. Since milk may be substituted for infant formula beginning at 6 months of age, the Department believes that a source of vitamin C should be included in the food package for infants beginning at 6 months of age. The Food Package Advisory Panel concurred with the Department, and to minimize the cost of the food package, further recommended that the Department authorize adult juices for infants and allow infant juices only when the need is documented by a compentent professional authority. The Department agrees with this recommendation and has incorporated it into the proposed regulation.

Women and Children

Currently there is one food package for pregnant, breastfeeding and non-breastfeeding postpartum women and children participating in the WIC Program. In developing this food package, the Department intended that competent professional authorities at local agencies would tailor the food packages according to individual needs. However, the Department believes that little tailoring is taking place. Because of the limited funds available, the Department believes that it is necessary to ensure that the participants with the greatest needs who may benefit most by consuming the supplemental foods receive the greatest quantity and variety of foods. Therefore, the Department is proposing four different food packages, one for pregnant and breastfeeding women, one for non-breastfeeding postpartum women, one for children and one for children with special dietary needs.

Many recommendations have been made in recent years to encourage women to breastfeed their infants. These recommendations have been

made on the basis of nutritional and immunological properties of breastmilk as well as other factors. The American Academy of Pediatrics recommends that full-term newborn infants be breastfed, except if there are specific contraindications. [18] In an effort to put recommendations for breastfeeding into practice and because the nutritional needs of pregnant and breastfeeding women are greater than the nutritional needs of non-breastfeeding postpartum women, the Department is proposing an enhanced food package for pregnant and breastfeeding women but not for non-breastfeeding postpartum women.

The proposed food package for pregnant and breastfeeding women provides the currently authorized foods in the currently authorized quantities with the exception of eggs, (for which the quantity is reduced for administrative reasons) plus dried beans or peas or peanut butter. The mature dried beans or peas or peanut butter will provide an additional source of nutrients and add variety to the food package. Although the proposed food package for non-breastfeeding postpartum women provides the currently authorized foods, the maximum authorized quantities of milk, eggs and juice are less than currently authorized. Additionally, mature dried beans or peas or peanut butter are not provided in the food package for non-breastfeeding postpartum women. The proposed food package for children also provides the currently authorized foods although the quanities of milk and eggs are less than currently authorized. Mature dried beans or peas or peanut butter are also provided in the food package for children as an additional source of nutrients and for variety. The proposed food package for children with special dietary needs is the same as the current food package for these children.

The food packages for pregnant and breastfeeding women, non-breastfeeding postpartum women, children and children with special dietary needs ar discussed by food item.

Eggs: The number of eggs currently authorized in the food package for women and children, 2½ dozen, has not been received well by many local agencies, primarily due to the administrative problem of purchasing one-half dozen eggs. Some grocery stores have a store-wide policy prohibiting the breaking of egg cartons. To alleviate this problem, the Department has allowed local agencies to issue 2 dozen eggs one month and 3 dozen eggs the next month when necessary. However, this monthly variation has caused some problems with issuance records and the automated printing of vouchers. To alleviate these problems the Food Package Advisory Panel recommended that 2 dozen eggs be provided in the food packages. The Department concurred with this recommendation and is proposing that 2 dozen eggs be provided in the food packages for pregnant and breastfeeding women, non-breastfeeding postpartum women and children.

Milk. The Advisory Panel believed that the amount of milk currently provided for children, 28 quarts, is excessive. The amount of milk that children should drink cannot be stated with convincing accuracy. This is partly because it depends to a large extent on economic factors and the availability of other foods. However, when a mixed diet is available in adequate quantities, milk consumption should probably not exceed one-third of the total daily calorie intake after the latter part of the first year of life (2 or 3 glasses a day).[19] If the major portion of a child's caloric needs are provided from a single food source, such as milk, other foods including those rich in iron may be excluded from the diet. Therefore, the Department is proposing that the amount of milk authorized for children be reduced to 24 quarts per month. This reduction will still provide more than 3 glasses of milk per day for those children who may need it. Additionally, the Department is proposing a reduction in the amount of milk authorized for non-breastfeeding women because they do not need as much milk as pregnant and breastfeeding women.

The Department has received a number of requests from Program participants and industry for the inclusion of goat milk as a substitute for cow milk in the food packages. The basis for these requests has been that some individuals who cannot tolerate cow milk can do quite well on goat milk. However, the Department is concerned because much of the commercially available goat milk is not pasteurized and most of it is not fortified with vitamin D. Therefore, in order to allow for the provision of goat milk it would be necessary to make an exception to the current requirements that milk provided to participants be pasteurized and fortified with vitamin D. Additionally, goat milk is a relatively poor source of folacin. Because milk is the major source of calories for infants, experts in the field of nutrition recommend that infants fed goat milk receive a folacin supplement. [20] As there is no assurance that infants fed goat milk would receive supplemental folacin, the Department is concerned about the possibility that infants receiving goat milk may develop a folacin deficiency which may result in megaloblastic anemia. Additionally, the cost of goat milk is more than twice the cost of cow milk.

Since a number of infant formulas designed for individuals with special needs are provided for infant and children participants, the Department questions the need for allowing goat milk. Therefore, the Department requests that comments be submitted on the need for goat milk for nutritional reasons why special formulas are not a satisfactory alternative for infants and children who cannot tolerate cow milk, the demand for goat milk for non-nutritional reasons, the availability of goat milk and, if goat milk is available, whether it is pasteurized or fortified with vitamin D.

These comments will be considered in making a decision on whether to allow for the provision of goat milk in the WIC food packages.

Cheese. Some participants have requested that additional cheeses be provided in the food packages. Brick cheese and Spanish White cheese have been specifically requested. The Food Package Advisory Panel recommended that the choices for cheese be expanded to include these cheeses if they are comparable to currently authorized cheeses in nutrient content and cost. Since the nutrient content of Spanish White Cheese varies from region to region, this cheese has not been added to the food packages. However, brick cheese is comparable in nutrient content to currently authorized cheeses and has been added to the list. After considering the nutrient content of other domestic cheeses available, the Department has decided to also add the following domestic cheeses: Edam, Gouda, Muenster, Provolone and Mozzarella part skim or whole.

Peanut Butter and Mature Dried Beans and Peas. In the past, the Department has received comments requesting a greater variety of foods in the food package. Mature dried beans and peas and peanut butter have been frequently requested. Because the Department has proposed a reduction in the number of eggs in the food packages for pregnant and breastfeeding women and a reduction in the number of eggs and quantity of milk in the food package for children, it is felt that an additional food, preferably a protein source, should be included in these food packages. Therefore, the Department proposes to add 1 pound of mature dry beans or peas or 18 ounces of peanut butter to the food packages for children and pregnant

and breastfeeding women. These foods are readily acceptable to most of the target population, will allow for cultural differences in diet patterns and will complement the use of other foods. Furthermore, mature dried beans and peas provide a source of zinc in American diets. Although there are other foods that contain zinc in higher concentrations, such as meat, administrative factors as well as cost, prohibit their inclusion in the food package.

Juice. The proposed regulations maintain the current requirements for authorized juices. The quantities of juice provided in the food packages are not changed except in the food package for non-breastfeeding postpartum women where there is a reduction in the quantity of juice provided. The sizes and packaging of juices make it extremely difficult to designate a maximum amount of juice which accommodates both single strength and frozen concentrated types. The Department considered designating a separate maximum amount for each type of juice. However, this would not allow participants to purchase a combination of types of juices. Therefore, one quantity is authorized for all types of juices. The Department is aware that participants receiving frozen concentrated juice receive slightly less juice than if single strength juice were used. However, because a maximum amount of juice is authorized, it does not mean that the maximum amount must be given to each participant each month. Further, over 100 percent of the RDA for vitamin C is provided in all food packages, even when slightly less juice is issued.

Additional Foods. Previously, the Department had not considered providing an enhanced food package for pregnant and breastfeeding women and children, believing that the food packages provided sufficient supplemental foods for these categories of participants. However, the Department is concerned about the adequacy of the current food packages in terms of some micronutrients and fiber supplied. Therefore, the Department gave consideration to additional food items which could be included in the food packages. Principally, the Department considered the addition of vegetables or whole grain breads. These food items were viewed in terms of nutritional contributions, nutrition education goals, cultural eating patterns, cost and administrative feasibility.

Vegetables are important dietary sources of vitamins A and C and fiber. However, individual vegetables differ widely in how much of these vitamins and fiber they provide. Dark green and deep yellow vegetables are good sources of vitamin A. Most dark green vegetables are reliable sources of vitamin C, if not overcooked, and are valued for riboflavin, folacin, iron and magnesium. Additionally, certain greens, including collards, kale, mustard, turnip and dandelion greens, provide calcium. The amount of fiber in vegetables depends on the cellulose, hemicellulose and lignin content of the vegetables.

Whole grains are important sources of B vitamins and iron. They also provide protein and contribute magnesium, folic acid, zinc and fiber to the diet. Although enriched white bread contains appropriate levels of many B vitamins, it generally does not contain the fiber and trace minerals that are found in whole grain breads. Therefore, it is beneficial to include some less refined or whole grain products in the diet.

Providing either vegetables or whole grain breads would be consistent with the principles of nutrition education since an additional food item would further the concepts that: (1) no one food should provide all the needed nutrients, and (2) a well balanced diet chosen from a variety of conventional foods is the preferred source of adequate nutrition. Exposure of participants to vegetables or whole grain bread in conjunction with nutrition education would be beneficial since participants may learn to make them a regular part of their diet.

In the decision as to whether vegetables or bread should be included in the package, administrative feasibility, nutrient content, cost and participant acceptability became important considerations. Following the second National WIC Symposium held by the Children's Foundation, the Department received numerous communications from nutritionists and administrators concerning the administrative difficulty of providing vegetables in the food package. Some of the difficulties brought to the Department's attention were that listing specific vegetables on vouchers would be cumbersome, monitoring vendors to ensure only authorized vegetables are provided to participants would be difficult and, in areas where dairies are used for home delivery, it may not be possible to provide vegetables.

The Department was also concerned that there would be an acceptability problem with vegetables. Many of the vegetables which contain high concentrations of the specified nutrients are the least popular. Although a major purpose of including vegetables would be to encourage their consumption, because of the relatively short time for many participants in the Program, especially pregnant women, the use of resources may be better placed in foods that have a higher probability of being consumed. Another concern was the level of salt in some canned vegetables. However, the Department would like further input from the public on this issue, and therefore, requests comments on the provision of vegetables to pregnant and breastfeeding women and children, the types of vegetables which should be provided and the quantity.

The Department gave further consideration to adding whole grain breads to the food packages for pregnant and breastfeeding women and children. However, for most breads considered by the public to be whole grain, there is no assurance that this is actually the case.

Standards of identity are definitions of foods developed by the Food and Drug Administration. They define what a food product is, its name and the ingredients which must be used, as well as optional ingredients and what must be declared on the label. There are standards of identity for whole wheat and cracked wheat flours which ensure that the proportions of the natural constituents of the wheat, other than moisture, remain unaltered. Additionally, there is a standard of identity for whole wheat bread which ensures that the only flours used in whole wheat breads are whole wheat flours. However, there is no standard of identity for cracked wheat bread. A review of ingredients statements on bread labels revealed that some breads labeled cracked wheat bread contain wheat flour (not cracked wheat) as the primary ingredient.

The situation is more complex in relation to rye bread and pumpernickel bread. Ingredient statements on rye breads and pumpernickel breads include rye flour and pumpernickel flour, respectively. Both rye flour and pumpernickel flour are made from rye grain. However, there are not standards of identity for rye flour or pumpernickel flour which establish the proportions of natural constituents in the flour. If the flour does include the bran and germ, the proportions of these constituents may vary. Furthermore, rye bread and pumpernickel bread are normally blends of wheat flour and rye flour or pumpernickel flour.

The rationale for considering including whole grain breads in the food packages for pregnant and breastfeeding women and children was to provide an additional source of fiber and trace

minerals provided by whole grains in the food packages. However, there is no assurance that cracked wheat, rye and pumpernickel breads contain substantial quantities of the bran or germ of the grain, and therefore, fiber and trace minerals. Furthermore, there is no assurance of uniformity among products labeled cracked wheat, rye or pumpernickel bread. Therefore, the Department is not considering proposing including cracked wheat, rye and pumpernickel bread in the food packages for pregnant and breastfeeding women and children. Because the standard of identity for whole wheat bread ensures that breads labeled whole wheat are whole grain breads, the Department is considering adding 2 pounds of whole wheat bread to the food packages for pregnant and breastfeeding women and children. However, the Department is concerned about the acceptability of whole wheat bread by participants and possible problems with the availability of whole wheat bread in rural areas. Therefore, the Department requests comments on the inclusion of 2 pounds of whole wheat bread in the food packages for pregnant and breastfeeding women and children especially in relation to acceptability and availability. These comments will be used in making a decision on whether to include whole wheat bread in these food packages.

Cereals. The cereals authorized for use in the WIC Program have always been a source for comment. After interim regulations were published in January 1976 there were requests from the cereal industry and the public to reduce the iron requirements to allow a larger variety of cereals to be used in the WIC Program. The establishment of a limitation for sugar was also requested by the public during several comment periods. While the Department made no changes at that time, it allowed State agencies to exclude any cereal they found unacceptable for use in the Program.

Although the proposed rules published in February 1977 did not contain any changes in the cereal requirement, again there were comments requesting a lowering of the iron requirement and establishment of a sugar limitation. In June 1977 public hearings were held by the Food and Nutrition Service to obtain comments regarding possible legislative changes in the WIC Program. During those hearings, 114 commenters representing a variety of interests presented oral or written testimony on various aspects of the food packages. These comments centered most often on the authorized cereals and their nutrients. A petition sent to the Department in June 1977 by a number of nutritionists, requested various changes in the cereal requirements related to the iron and sugar levels. FNS officials met with representations from this group to discuss their concerns and the action the Department would take. A decision was made to include in the preamble of the final regulations a discussion of possible changes in the cereal requirements as issues for public comment.

Therefore, in the final WIC Program Regulations published in the Federal Register on August 26, 1977, the Department requested comments concerning a number of possible changes in the requirements for cereals authorized in the WIC Program. These possible changes included reducing the iron requirement, establishing a maximum sugar level, eliminating cereals which provide 100 percent of the USRDA's for certain nutrients, allowing whole grain cereals regardless of iron content, and excluding cereals with artificial flavors and colors. Due to the complexity of this issue and the Department's desire to obtain the maximum possible advice, the Food Package Advisory Panel also discussed this issue and presented a number of recommendations to the Department.

Many factors were considered in the evaluation of the appropriateness of the requirements for authorized cereals. Possible changes had to be considered in the context of the purpose of the WIC Program and its supplemental nature. The Food Package Advisory Panel strongly recommended that all items included in the food packages be evaluated not only in terms of nutritional content as related to participants' needs, but also in view of the Program's educational objectives and economic ramifications. The Department used these criteria in formulating the requirements for cereals being proposed.

The Department considered the following major goals in this decision process:

1. To provide an economical and acceptable source of iron;
2. To meet the legislative intent of ensuring an appropriate level of sugar;
3. To ensure that the cereals are compatible with the nutrition education messages of the Program;
4. To increase the variety of cereals thereby increasing participant consumption of cereals.

The issues concerning the cereals are discussed below in relation to these goals.

Iron. Iron deficiency is one of the most prevalent nutritional problems in the WIC Program target population. In order to provide an acceptable and economical source of dietary iron, cereal is included in the food packages for women and children. Currently, cereals must contain a minimum of 45 percent of the USRDA for iron in order to be authorized. This requirement was established to ensure that the cereals provided to WIC Program participants would contain considerable quantities of iron and to ensure a variety of cereals could be offered to allow for differences in preferences among participants. However, the Department has received numerous requests from State agencies, nutritionists and participants to lower the iron requirement for cereals because the current requirement does not allow for a large enough variety of cereals from which participants may choose. The Department is concerned about these requests since this lack of variety in cereals has a potentially adverse affect on consumption of cereals by participants.

In order to gain further insight into the potential problem, in August 1977, the Department requested comments on whether it should reduce the iron requirement for cereals from 45 percent to 25 percent of the USRDA for iron. Of the 150 comments received, 81 percent supported a reduction in the iron requirement. Many of these commenters stated that the cereals currently authorized are not readily accepted by participants and that iron consumption could even be increased with a reduced iron requirement, since the more popular cereals that would be allowed would be more likely to be consumed. Those opposed to the reduction in the iron requirement stated that it would be contrary to the goal of the WIC Program which is to provide foods which are good sources of nutrients lacking in the diets of the target population.

The Department decided that further investigation of the issues raised by commenters would be necessary to make an informed decision on whether to lower the iron requirement for cereals. Therefore, the Department compiled information on the numbers of cereals which would be authorized at 45 percent and 25 percent of the USRDA for iron, the acceptability of the currently authorized cereals, the prevalence of iron deficiency in the WIC Program target population and the impact reducing the iron requirement for cereals would have on the iron provided by the food packages. The information the Department compiled as a result of this effort is discussed in the following paragraphs.

The Department examined approximately 100 cereals that are

currently available on the commercial market to determine the number of cereals which contain a minimum of 45 percent and 25 percent of the USRDA for iron. Of these, 20 contained a minimum of 45 percent of the USRDA for iron and 52 contained a minimum of 25 percent of the USRDA for iron. However, some of the cereals examined are not available in all areas of the country and State agencies frequently limit the number of cereals available by excluding highly sugared cereals from the food package. Therefore, the number of cereals authorized for participants to choose from can be much less than these figures imply. Data abailable from 29 State agencies indicate that with the current requirement that cereals contain a minimum of 45 percent of the USRDA for iron, the average number of available cereals is 6 for those restricting sugar levels and 9 for those not restricting sugar levels.

To assess the acceptability of currently authorized cereals, the Department reviewed data obtained from a major study of the WIC Program, redemption rates of cereal vouchers, surveys and interviews with participants.

In 1976, the Urban Institute performed a study to evaluate the WIC Program delivery systems. As part of this study participants were interviewed to obtain information on participant satisfaction with the foods in the WIC packages. These interviews revealed participant dissatisfaction with WIC cereals. According to the report, 23 percent of the participants surveyed requested that cereal be dropped from the food package or that the amount provided be decreased. (21)

Data from a State agency on the redemption rates of cereal vouchers in March, 1979 indicate that 18 percent of these vouchers were not issued or were voided at the local agency while only 2.4 percent of other vouchers were not issued. Reasons for this included: dislike of the cereals, cereals from previous months were not used or failure to pick up vouchers. Of the cereal vouchers issued, 10 percent were not redeemed, while the nonredemption rate for all foods was 4.5 percent. Therefore, 28 percent of the WIC vouchers for cereals in this particular State agency were not being used.

Small scale surveys conducted by State or local agencies indicate dissatisfaction with the WIC cereals. A survey conducted in Tennessee in 1979 showed that 10 percent of the participants do not use the WIC cereals. Another small survey from Rhode Island revealed that 13 percent of the WIC child participants do not eat the cereals provided.

Interviews of participants at local agencies in California, Washington, Oregon, Arizona and Nevada performed by the Western Regional Office since January, 1979 also indicate problems with the acceptability of cereals currently authorized under the WIC Program. When asked about the food package, participants criticized the types of cereals provided and expressed a need for a wider selection of cereals.

Although the WIC cereals need not be those most favored by participants, acceptability is important because there is a small number of cereals actually available for participants to choose from and these cereals will probably be consumed for at least six consecutive months. The above data indicate that the acceptability of the cereals is not as high as it should be to ensure that participants receive maximum benefits from the WIC food packages. While participants may be making independent purchases of other cereals or foods, the Department has no evidence which shows that alternate sources of iron are being consumed.

Several national studies and surveys have shown that iron deficiency is a major nutritional problem among the WIC Program target population. The *Ten State Nutrition Survey* reported a high prevalence of low hemoglobin levels, particularly among the lowest income groups. Low hemoglobin values were believed to be due primarily to iron deficiency because of the age distribution and low iron consumption indicated by dietary information. (*22*) The study *Nutritional Status of Preschool Children in the United States (Preschool Nutrition Survey)* found evidence of low hemoglobin levels among preschool children of lower socioeconomic status. (*23*) Results of the *Health and Nutrition Examination Survey* also indicate that iron deficiency is a problem among the WIC Program target population. The prevalence of low hemoglobin values in preschool children and women was generally higher for the poverty group than for the nonpoverty group. Dietary consumption data revealed lower mean iron intakes among black preschool children and women in the poverty group than among other ethnic/income groups. This was due to consumption of a smaller amount of food rather than a lower iron content of the foods consumed. (*24*)

Studies which have been performed to evaluate the effectiveness of the WIC Program indicate improvement in iron consumption with participation in the Program. The University of North Carolina performed a medical evaluation of the WIC Program at 19 local agencies in 14 States. The investigators concluded that there was a consistent increase in hemoglobin levels and a reduction in the prevalence of anemia in infant and children participants. Additionally, an increase in mean hemoglobin concentration and a reduction in the anemia rate was reported for pregnant and postpartum women. (*25*) A study performed on WIC participants in Massachusetts showed similar results. (*26*) A number of State and local agencies have also reported decreases in the prevalence of anemia in the target population after participation in the WIC Program.

At the request of the Department, the Center for Disease Control (CDC) used data from its Nutrition Surveillance System to estimate some nutritional effects of the WIC Program. On the basis of this data CDC reported that children entering the WIC Program have a high prevalence of anemia, presumably caused by iron deficiency, and that children enrolled in the Program for 1 year experience considerable improvement in their hemoglobin and hematocrit values. (*27*)

Currently, the total food package for women and children provides approximately 12 mg. of iron per day. With the addition of dried beans or peas or peanut butter and cereals which contain 25 percent of the USRDA for iron, the food packages for pregnant and breastfeeding women and children would provide approximately 8 mg. of iron per day, which is 53 percent of the RDA for iron for children 1–3 years of age, 80 percent of the RDA for children age 4 and 27 percent of the RDA for iron for pregnant and breastfeeding women.*

The cereals providing 45 percent or more of the USRDA for iron would still be available if the minimum requirement for iron were lowered to 25 percent of the USRDA. Therefore, these calculated

* The RDAs' for iron for pregnant and breastfeeding women in the 1974 edition of the *Recommended Dietary Allowances* are 18 + and 18 mg. of iron per day, respectively. The 1979 edition of the *Recommended Dietary Allowances* does not specify a dietary requirement for iron. The Food and Nutrition Board states that, "The increased requirement (for iron) during pregnancy cannot be met by the iron content of habitual American diets nor by the existing iron stores of many women; therefore the use of 30–60 mg. of supplemental iron is recommended. Iron needs during lactation are not substantially different from those of non-pregnant women, but continued supplementation of the mother for 2–3 months after parturition is advisable in order to replenish stores depleted by pregnancy." (*28*) Therefore, 30 mg. per day was used as the RDA for iron in the calculations for pregnant and breastfeeding women. If 18 mg. of iron per day is used as the RDA for pregnant and breastfeeding women the proposed food package would provide 44 percent of the RDA for iron for pregnant and breastfeeding women.

iron levels represent a minimum level in the package. Participants selecting the more highly fortified cereal would obtain a higher percentage of their requirement for iron.

Concern about lowering the iron requirement for authorized cereals and therefore lowering the iron content of the total food packages has centered on the beneficial effect WIC has been observed to have on reducing the prevalence of anemia among pregnant women and children. The Department does not want to jeopardize the success of the WIC Program in positively affecting anemia rates. However, the Department is concerned about the low acceptability of currently authorized cereals by particpants.

Participants in the WIC Program are certified as being at nutritional risk for a number of reasons; iron deficiency is only one nutritional risk criteria used in certification. The Department believes that it would be acceptable to allow particpants who are not iron deficient to receive cereals which contain 25 percent of the USRDA for iron. Although the Department does not have data to indicate that these participants are consuming foods high in iron, it would be reasonable to assume that participants who do not exhibit signs of iron deficiency either have sufficient iron stores to protect against iron deficiency or are obtaining a sufficient amount of iron through their diets or in a medicinal form. Therefore, the Department believes that for participants who are not iron deficient, acceptability of cereals outweighs the need for cereals which contain a large amount of iron and is proposing that participants who at certification do not exhibit signs of iron deficiency be able to receive cereals which contain a minimum of 25 percent of the USRDA for iron.

Acceptability of cereals is also important for participants who are iron deficient. However, the Department believes that more concrete evidence of low acceptability of currently authorized cereals would be necessary to lower the iron requirement for cereals provided to participants who are iron deficient. Cereals are the primary source of iron in the food packages for women and children participants. Lowering the iron requirement for cereals provided to participants who are iron deficient may have a negative impact on the effectiveness of the WIC Program in reducing the prevalence of iron deficiency. Therefore, the Department is proposing that participants who at certification exhibit signs of iron deficiency be limited to receiving cereals which contain a minimum of 45 percent of the USRDA for iron. The Department recognizes that participants who exhibit signs of iron deficiency should be treated with medicinal iron supplements and this proposal does not intend to minimize the need for such supplementation. However, a survey has indicated that many clinics do not routinely prescribe medicinal iron supplements. (*29*) The Department believes that it is appropriately the role of the health community and not necessarily that of the USDA to provide such supplements. By maintaning the higher iron requirement in cereals for participants who exhibit signs of iron deficiency, the Department hopes to have some effect on the iron status of these participants. The Department's requirements for foods provided through the WIC Program are minimum requirements. State and local agencies can establish more stringent requirements if the desire. Therefore, State or local agencies can require that participants who do not exhibit signs of iron deficiency, but who are considered to be at risk, be restricted to receiving cereals fortified at a minimum of 45 percent of the USRDA for iron.

The final decision on the iron level in cereals will be a difficult one to make. The Department, therefore, requests comments from all interested parties, such as clinics, participants, and medical and nutritional experts, in order that the final decision made by the Department reflect the goals of the WIC Program and meet the needs of the participants.

Bioavailability of Iron

Since cereals provide the largest amount of iron in the WIC food package, the Department is concerned about the bioavailability of iron used to fortify cereals. Bioavailability of iron from foods is a complex subject. The bioavailability of iron used in fortification is influenced by many factors including the chemical form of the iron, particle size, interaction of the iron with other dietary components, chelation, the body's need for iron, processing and the digestibility of the food supplying the iron. (*30*) The same form of iron, when used in different cereals, may have different availabilities. Iron bioavailability is generally expressed as a relative biological value (RBV). Ferrous sulfate is used as the standard of comparison and assigned an RBV of 100. Some scientists suggest that the forms of iron used to fortify grain products be limited to those with RBVs' of 50 or greater. (*31*)

Communications between USDA nutritionists and industry representatives indicate that the forms of iron most commonly used to fortify breakfast cereals are ferric orthophosphate and reduced iron, including hydrogen reduced iron and electrolytically reduced iron. Ferric orthophosphate is generally considered to have poor availability. However, the bioavailability of ferric orthophosphate is affected by particle size and solubility, and ferric orthophosphate samples can differ widely within these parameters. When samples of ferric orthophosphate of small particle size and with good solubility have been used, fair bioavailability has been reported. The availability of reduced iron also varies. Properties of reduced iron that have been suggested to be important in determining its bioavailability include the method of manufacture, particle size, solubility, chemical impurities, surface area and age of the iron. Because the bioavailabilities of ferric orthophosphate and reduced iron each vary, the RBVs' for these forms of iron are expressed as ranges. The RBV for ferric orthophosphate has been reported to be 3 to 46, the RBV for hydrogen reduced iron has been reported to be 18 to 54 and the RBV for electrolytically reduced iron has been reported to be 45 to 76. (*32*)

Communications between USDA nutritionists and industry representatives have indicated that minimally available sources of iron have been removed from most cereals and the reduced iron used in at least some cereals is of small particle size. However, without exact specifications on the forms of iron used to fortify cereals, it is impossible to determine if the iron is poorly or moderately to well absorbed. The Food and Drug Administration is working on the standards for the forms of iron used in food fortification.

The Department is very concerned that the iron used to fortify some cereals may have poor availability. However, data which is currently available is not sufficient to substantiate poor availability, and is therefore not sufficient to warrant the removal of these cereals from the WIC food packages. The Department intends to pursue the issue of bioavailability of iron from cereals and requests that manufacturers of adult cereals and infant cereals submit information on specifications for iron used to fortify their products and submit data, where available, on iron bioavailability from their cereals. The Department will compile this information and identify needs. Once research needs have been

identified, the Department will perform research on the bioavailability of iron from cereals. If the results of this research show that the bioavailability of iron from some cereals is poor, the Department will give serious consideration to removing these cereals from the WIC food packages at that time.

Sugar. With the proposal to allow lower levels of iron fortification for some participants, the level of sugar in cereals becomes an extremely important consideration since many highly sweetened cereals would be authorized. When public comments were requested in August 1977, the Department received 230 comments on the exclusion of high sugar cereals from the food packages. Over 90 percent of the comments (208) were in support of the Department establishing a maiximum level of sugar for cereals authorized in the WIC Program. These comments were received from State agencies, local agencies, the general public, and interest groups. There were 22 comments received from State and local agencies and interest groups, including the Sugar Association and two cereal companies, opposing the establishment of a maximum level of sugar in cereals.

Commenters supporting the elimination of high sugar cereals from the WIC Program believe high sugar cereals may contribute to health problems such as dental caries and obesity. Commenters opposed to the elimination of high sugar cereals believe current research does not support the relationship between sugar consumption and health problems. Additionally, they believe that the elimination of high sugar cereals would reduce the number of cereals authorized and diminish popularity and acceptability of WIC cereals. The Food Package Advisory Panel, in considering this issue, recommended that a maximum level of sugar be set.

Several recent reports have emphasized the need for concern about the amount of sugar in the diet. The *Evaluation of the Health Aspects of Sucrose as a Food Ingredient*, prepared for HEW by the Federation of American Societies for Experimental Biology concluded that:

> Reasonable evidence exists that sucrose is a contributor to the formation of dental caries when used at the levels that are now current and in the manner now practiced. (*33*)

A symposium sponsored by the American Society for Clinical Nutrition entitled *Can Diseases of Over Consumption be Prevented by Dietary Changes?—A Critique of the Evidence* states that:

> Evidence is convincing that sucrose, especially when consumed frequently throughout the day, is the dietary component that is most conductive to (oral) bacterial infection and caries . . . While the frequency and pattern of diet consumption are powerful determinants of caries induction, the absolute amount and nature of the sugar consumed also is important.

This report concludes that:

> Reduction of frequency of sucrose consumption results in reduced dental caries without known risk. The benefits of reduction of consumption of other simple sugars and carbohydrate containing foods have been more difficult to establish. (*34*)

Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention states:

> (a) Cause of concern is the diet of a large proportion of today's children—containing considerably more fat and sugar than a reasonable diet should have.

It suggests that:

> Excessive intake of salt, sugar, and fats should be avoided . . . Sweets in the diet should be limited to prevent tooth decay.

The report summarizes its suggestions on good nutrition by stating among other things that:

> Americans would probably be healthier, as a whole, if they consumed * * * less sugar * * * (*35*)

Commenters supporting the elimination of high sugar cereals from the WIC Program believe that the provision of high sugar cereals is contrary to nutrition education prinicples and may lead to the development of unsound eating practices. The Food Package Advisory Panel and the Department agree that the nutrition education goals of the WIC Program support reducing the level of sugar in cereals.

In addition, highly sugared cereals are more expensive than cereals containing less sugar. As the sugar contents of cereals increases, the average cost of the products also increases. While consumers may opt to add their own table sugar to the cereals authorized by WIC Program, this is a conscious decision made by the consumer, and is a more economical way to buy sugar. Therefore, if highly sugared cereals are allowed, the food packages themselves are inconsistent with the goal of teaching participants economical food buying patterns.

The Department recoginzes that the juice in the food packages also contains sugar. However, the sugar in juice cannot be easily reduced since most sugar in juice is naturally occuring. Since much of the sugar in cereal is added, the percentage of sugar in cereal can be reduced.

The majority of commenters who recommended a maximum level of sugar for cereals authorized in the WIC Program recommended that this level be established at 15 or 20 percent. Percentage figures were most often used to express the recommended level of sugar because they are most easily understood, but for practical purposes they must be converted to correspond to the figures used in nutrition labeling so that information found on cereal packages can be used to identify acceptable cereals. The converted percentages for 15 and 20 percent are equal to 4.25 and 5.67 grams of sugar per ounce of cereal, or, rounded to whole numbers, 4 and 6 grams per ounce. The higher value of 6 grams of sugar per ounce of cereal is the same as that recommended by the Food Package Advisory Panel.

The Department collected information on the sugar content of cereals that are currently available on the market. There does not appear to be a clear cut-off point to differentiate low sugar cereals from high sugar cereals. With the current iron requirement of 45 percent and a 4 grams per ounce sugar limit, only 10 cereals would be authorized. Based on a 6 grams per ounce limit, 12 cereals would be authorized. With the proposed 25 percent iron requirement for some participants and a 4 grams per ounce sugar limit, 18 cereals would be authorized. Based on a 6 grams per ounce sugar limit, the list increases to 26 cereals. The Department has decided to propose a sugar limit of 6 grams per ounce of cereal which is the least restrictive limit recommended by the commenters and the same as that suggested by the Food Package Advisory Panel. When coupled with the proposed iron requirement of 25 percent of the USRDA for participants who at certification do not exhibit signs of iron deficiency, this less restrictive limit allows for a wider variety of cereals. It is proposed that the maximum level of sugar allowed in cereals authorized for use in the WIC Program be 6 grams per ounce of dry cereal. Sugar, as used in this proposal, means "sucrose and other sugars." This is the terminology industry uses to label cereals. Therefore, acceptable cereals should be easy to identify. The term "sucrose and other sugars" includes simple sugars (monosaccharides and disaccharides) added to or contained in the products.

This proposal reflects the concerns of the majority of public comments previously received, is consistent with the Food Package Advisory Panel's recommendations, and is consistent with the overall purpose of the WIC

Program. That purpose, to provide supplemental nutritious food and nutrition education as an adjunct to health care during critical periods of development in order to prevent the occurrence of health problems and improve health status, will be better met by this proposal. Since WIC Program participants have demonstrated nutritional problems and are at risk, it is critical that the Department provide exemplary food choices to supplement participants' diets and serve as nutrition education messages in themselves.

Whole Grain Cereals. In response to the request for comments on the inclusion of whole grain cereals regardless of iron content, the Department received 114 comments. Eighty comments supported the inclusion of whole grain cereals regardless of iron content, while 34 comments opposed including whole grain cereals if they did not meet the iron requirement.

Commenters who supported the inclusion of whole grain cereals regardless of iron content stated that these cereals would increase the fiber content of the food packages as well as provide a source of B vitamins and trace minerals. Commenters who opposed the inclusion of whole grain cereals if they did not meet the iron requirement questioned the benefits of including whole grain cereals at the expense of the iron content of the package. These commenters also stated that many whole grain cereals provide less fiber, B vitamins and trace minerals than the fortified cereals currently authorized.

Inclusion of whole grain cereals regardless of iron content would allow the use of some popular cereals in the WIC Program, and therefore, be acceptable to many people. To allow the inclusion of whole grain cereals regardless or iron content would, however, drastically reduce the amount of iron provided below the level provided by the current package.

Additionally, there are no standards of identity for whole grain cereals. Therefore, problems similar to those discussed in the section of this preamble on whole grain bread would be encountered if the Department were to allow whole grain cereals regardless of iron content. The Food Package Advisory Panel rcommended that the Department not allow whole grain cereals which do not meet the iron requirement. The Department agrees with this recommendation and is proposing to authorize only those whole grain cereals which meet the iron requirement and sugar limitation. The Department is requesting comments on the inclusion of whole wheat bread in the food packages for pregnant and breastfeeding women and children. If a decision is made to include whole wheat bread, an additional source of fiber, B vitamins and trace minerals would be provided in these food packages.

Highly Fortified Cereals. The Department received 105 comments on the exclusion of highly fortified cereals. Sixty-three comments from local and State agencies and interest groups supported the exclusion of highly fortified cereals. Nine comments from local and State agencies and interest groups supported exclusion of these cereals only for children under four years of age. Three comments from a State agency and local agencies supported exclusion of highly fortified cereals which contain 100 percent of the USRDA for vitamin A and/or vitamin D. Thirty comments from local and State agencies and the general public opposed the exclusion of highly fortified cereals.

Commenters who supported the exclusion of highly fortified cereals stated that the provision of one food containing 100 percent of the USRDA for certain nutrients may be confusing to participants because participants are encouraged, through nutrition education, to consume a diet consisting of a variety of foods to obtain needed nutrients. Commenters who supported the exclusion of highly fortified cereals for children under four stated that cereals which are fortified at 100 percent of the USRDA for adults and children four or more years of age supply greater than 100 percent of the USRDA for children under four years of age. Commenters who supported exclusion of cereals which contain 100 percent of the USRDA for vitamin A and/or vitamin D stated that the high levels of vitamin A and/or vitamin D in these cereals may contribute to toxicity in young children if the intake of these vitamins from other sources is also substantial. Commenters who opposed the exclusion of highly fortified cereals stated that the danger of toxicity from use of these cereals is minimal and would only occur if the child were taking a large daily dose of supplementary vitamins over a long period of time, in addition to consuming these cereals.

The Food Package Advisory Panel believed that the provision of cereals which contain 100 percent of the USRDA for any nutrient would conflict with the definition of a supplemental food program and that a single food should not provide the total daily nutrient requirement for participants. Therefore, the panel recommended that highly foritified cereals be excluded from all food package.

Vitamins such as the B vitamins and vitamin C are water soluble. When the intake of water soluble vitamins is greater than the amount needed by the body, the excess is excreted in the urine. Therefore, problems of toxicity are not found with water soluble vitamins. However, problems of toxicity can be exhibited when excessive quantities of fat soluble vitamins such as vitamin A and vitamin D are ingested. The Department is concerned about the possibility of toxicity resulting from excessive intakes of vitamin A or vitamin D.

Because of this concern, the Department considered restricting cereals for one to three year olds that contained more than 50% of the USRDA for vitamin A and vitamin D for adults and children four or more years of age. This would have eliminated four cereals. However in reviewing the available evidence the department found that cases of vitamin A and vitamin D toxicity in infants and young children have been uncommon in the U.S. Fomon et al. found that moderate overdoses of vitamin D in the range of 1380 to 2370 I.U., representing approximately three to six times the RDA for preschoolers, had no detrimental effect on growth. (*36*) Excessive intakes of vitamin D in the range of 50,000 to 100,000 I.U. daily have been shown to be potentially dangerous to children and adults. (*37*) Similarly for vitamin A, adverse effects have been shown to occur at levels 20 to 30 times the RDA for this nutrient. Most recent cases of vitamin A and D toxicity have been attributed to an excessive intake of a vitamin supplement. It would appear that only under unusual circumstances would vitamin toxicity be likely to occur in preschoolers. The Department has therefore decided not to restrict highly fortified cereals for one to three year olds. The Department is interested in comments on the question of highly fortified cereals.

Artificial Flavors and Colors. The Department received 103 comments on the exclusion of cereals which contain artificial flavors and colors. Fifty-seven comments from State and local agencies, interest groups and the general public supported the exclusion of cereals that contain artificial flavors and colors and thirty-six comments from State and local agencies opposed the exclusion of these cereals. Commenters in support of the exclusion of cereals which contain artificial flavors and colors stated that there may be a relationship of these food ingredients to health and behavior problems such as hyperactivity. Additionally, some commenters stated that artificial flavors and colors only

serve a cosmetic purpose and, therefore, are unnecessary. Commenters who opposed the exclusion of cereals with artificial flavors and colors stated that there is insufficient evidence on which to base a restriction.

Dr. Ben Feingold has proposed the hypothesis that hyperkinetic behavior in children is related to a large variety of chemicals widely used by food processors as synthetic flavors and colors. The dietary regimen advocated by Dr. Feingold for the management of hyperkinesis specifies the exclusion of these synthetic food additives.(*38*) The Feingold hypothesis has received considerable attention but the issue of the effect of synthetic food additives on the health and behavior of children remains controversial. Early studies have been considered inconclusive because of shortcomings in study design. The later, more reliable studies may be interpreted to suggest that although there does appear to be a subset of children with behavioral disturbances who do respond to the Feingold diet, the specific elimination of synthetic food colors cannot be considered a major factor in the reported responses of a majority of these children.(*39*) Controlled clinical studies of the role of synthetic flavors in the Feingold diet have not been undertaken because of the difficulty of establishing double blind experimental conditions.(*40*)

The Department has decided to allow the inclusion in the food packages of cereals containing synthetic flavors and colors. At present the evidence is not strong enough to regulate in this area. If a parent is concerned about the consumption of products which contain synthetic flavors or colors by his/her child, (s)he can be advised of possible alternatives through nutrition education.

In summary, the proposed changes in requirements for cereals are: (1) a reduction in the iron requirement for cereals for participants who at certification do not exhibit signs of iron deficiency, from 28 to 15 milligrams of iron per 100 gram of dry cereal (45 to 25 percent of the USRDA for iron); and (2) the establishment of a maximum level of sugar at 6 grams per ounce dry cereal. Cereals which the Department knows currently meet the requirements are listed.

Cereal	Iron (percent of USRDA)	Sugar (grams per ounce)
Corn Total	100	3
Total	100	3
Product 19	100	3
Concentrate	80	3
Cream of Wheat, Regular	45	0
Cream of Wheat, Instant	45	0
Quick Cream of Wheat	45	0
Mix and Eat, Regular	45	0
Kix	45	2
Buc Wheats	45	5
Country Corn Flakes	45	3
Fortified Oat Flakes	45	5
(Cereals listed below are not authorized for anemic participants)		
Puffed Wheat*	25	1
Toastie O's*	25	1
Puffed Rice*	25	0
Cheerios*	25	1
Wheat Chex*	25	3
Special K*	25	2
Wheaties*	25	3
Grape Nut Flakes*	25	4
40% Bran Flakes*	25	5
Life*	25	5
Bran Chex*	25	5
Cinnamon Life*	25	6
All Bran*	25	8
Halfsies*	25	5

*These cereals are not authorized for participants exhibiting signs of iron deficiency.

The Department acknowledges that this list may be incomplete and requests industry to send it the current specifications on any additional cereals which meet the proposed requirements.

Food Packages

Each of the proposed food packages contains some or all of the supplemental foods described in the preceding section of this preamble in varying amounts appropriate for the different categories of participants. The food packages are described below. The quantities included in the descriptions are the maximum quantities authorized.

Food Package I—Infants 0 to 2–4 months. This food package provides 403 fluid ounces of iron fortified concentrated liquid infant formula. An extra 52 fluid ounces may be issued on an individual basis provided the need is demonstrated and documented by a physician. Equivalent amounts of powdered formula or ready-to-feed formula may be substituted in the amounts specified in the regulation.

Food Package II—Infants 2–4 to 6 months. This food package provides infant formula as described under Food Package I. Additionally, 24 ounces (dry weight) of infant cereal is provided.

Food Package III—Infants 6 to 12 months. This food package for older infants provides infant formula as described under Food Package I. Fluid whole milk, evaporated whole milk, dry whole milk or low calorie formula may be substituted for infant formula at the rates specified in the regulation. The extra 52 ounces authorized for infant formula does not apply to these substitutes. This food package also provides infant cereal as described under Food Package II. Additionally, 92 fluid ounces of single strength adult fruit juice are provided. Frozen concentrated fruit juice may be substituted for single strength fruit juice as long as the reconstituted volume is no greater than the amount authorized for single strength juice. Infant juice may be substituted for adult juice at the rate of 63 fluid ounces of infant juice per 92 fluid ounces of single strength adult juice provided the need is documented by the competent professional authority.

Food Package IV—Children 1 to 5 years. This food package provides 24 quarts of fluid whole milk or its substitutes as described in the regulation, two dozen eggs, 36 ounces (dry weight) of cereal, 276 fluid ounces single strength juice, and one pound of mature dried beans or peas or 18 ounces of peanut butter. Frozen concentrated juice may be substituted for single strength juice as long as the reconstituted volume is no greater than the amount authorized for single strength juice.

Food Package V—Children 1 to 5 with Special Dietary Needs. The food package for children with special dietary needs provides iron-fortified infant formula as described under Food Package I. Low calorie formula may be substituted for infant formula. However, the extra 52 ounces authorized for infant formula does not apply to low-calorie formula. This food package also provides 36 ounces (dry weight) of cereal and 138 fluid ounces of single strength juice. Frozen concentrated juice may be substituted for single strength juice as long as the reconstituted volume is no greater than the amount authorized for single strength juice.

Food Package VI—Pregnant and Breastfeeding Women. The food package for pregnant and breastfeeding women provides 28 quarts of fluid whole milk or its substitutes as described in the regulation, two dozen eggs, 36 ounces (dry weight) cereal, 276 fluid ounces of single strength juice, and one pound of mature dried beans or peas or 18 ounces of peanut butter. Frozen concentrated juice may be substituted for single strength juice as long as the reconstituted volume is no greater than the amount authorized for single strength juices.

Food Package VII—Non-breastfeeding Postpartum Women. The food package for postpartum women provides 24 quarts of fluid whole milk or its substitutes as described in the regulation, two dozen eggs, 36 ounces (dry weight) of cereal, and 184 fluid ounces of single strength juice. Frozen concentrated juice may be substituted for single strength juice as long as the reconstituted volume is no greater than

the amount authorized for single strength juice.

Commodities

This proposal includes provisions for the Department to purchase and distribute, at the request of a State agency, commodity foods. Funds allocated to the State agency will be used to purchase and distribute commodity foods which are requested. The commodity foods available to State agencies will be equivalent in quantity and quality to those authorized supplemental foods specified in the regulation.

Substitutions

Pub. L. 95–627 grants the Secretary the authority to approve a State agency's plan to substitute different foods which are nutritionally equivalent to the authorized supplemental foods in order to allow for different cultural eating patterns. This section of the legislation was written primarily to permit areas outside the continental United States to operate a WIC Program which provides foods indigenous to the area. This regulation proposes that any State agency which wants to make such substitutions submit to FNS a plan for the substitution of foods in keeping with the goals of the Program. Substitution requests will be reviewed by the Agency in order to be approved.

The current regulation concerning the food package will remain in effect until the proposed regulation is revised in response to comments received and the final regulation is published.

References

(1) Food and Nutrition Board, National Research Council, *Folic Acid; Biochemistry and Physiology in Relation to the Human Nutrition Requirement* (Washington, D.C.: National Academy of Sciences, 1977).

(2) Mildred S. Van de Mark and Audrey Clever Wright, "Hemoglobin and Folate Levels of Pregnant Teen-agers," *Journal of the American Dietetic Association* 61 (1972): 511–516.

(3) Food and Nutrition Board, *Folic Acid.*

(4) Food and Nutrition Board, *Folic Acid;* Howard E. Sauberlich, Richard O. Dowdy and James H. Skala, *Laboratory Tests for the Assessment of Nutritional Status* (Cleveland, Ohio: CRC Press, Inc, 1974).

(5) Food and Nutrition Board, National Research Council, *Recommended Dietary Allowances,* Eighth Edition (Washington, D.C.: National Academy of Sciences, 1974).

(6) *Ibid.*

(7) Harold H. Sandstead, "Zinc Nutrition in the United States," *American Journal of Clinical Nutrition* 26 (1973): 1251–1260.

(8) K. Michael Hambridge et al., "Zinc Nutrition of Preschool Children in the Denver Head Start Program," *American Journal of Clinical Nutrition* 29 (1976): 734–738.

(9) Steven N. Heller and L. Ross Hackler, "Changes in the Crude Fiber Content of the American Diet," *American Journal of Clinical Nutrition* 31 (1978): 1510–1514.

(10) Food and Nutrition Board, *Recommended Dietary Allowances,* Eighth Edition.

(11) Food and Nutrition Board, National Research Council, *Recommended Dietary Allowances,* Ninth Edition (1979, in Press), with the permission of the National Academy of Sciences, Washington, D.C.

(12) Comptroller General of the United States, *The Special Supplemental Food Program for Women, Infants and Children (WIC)—How Can It Work Better?* Publication No. CED–79–55 (Washington, D.C.: U.S. General Accounting Office, Distribution section, 1979).

(13) Samuel J. Fomon, Lloyd J. Filer, Jr., Thomas A. Anderson and Ekhard E. Ziegler, "Recommendations for Feeding Normal Infants," *Pediatrics* 63 (1979): 52–59.

(14) Committee on Nutrition, American Academy of Pediatrics, "Iron Supplementation for Infants," *Pediatrics* 58 (1976): 765–768.

(15) Samuel J. Fomon, "What are Infants Fed in the United States?" *Pediatrics* 56 (1975): 350–354.

(16) Committee on Nutrition, American Academy of Pediatrics, "Iron Supplementation for Infants."

(17) American Academy of Pediatrics and American Academy of Periodontics, "Juice in Ready to Use Bottles and Nursing Bottle Caries," *News and Comment,* a publication of the American Academy of Pediatrics 29 (January 1978): 11.

(18) Nutrition Committee of the Canadian Paediatric Society and the Committee on Nutrition of the American Academy of Pediatrics, "Breast-Feeding, A Commentary in Celebration of the International Year of the Child, 1979," *Pediatrics* 62 (1978): 591–598.

(19) Committee on Nutrition, American Academy of Pediatrics, "Should Milk Drinking by Children Be Discouraged?" *Pediatrics* 53 (1974): 576–582.

(20) Food and Nutrition Board, *Recommended Dietary Allowances,* Eighth Edition.

(21) Marc Bendick, Jr., Toby H. Campbell, D. Lee Bawden and Melvin Jones, *Efficiency and Effectiveness in the WIC Program Delivery System,* USDA Miscellaneous Publication No. 1338 (Washington, D.C.: USDA, 1976).

(22) U.S. Department of Health, Education, and Welfare, Public Health Service and Mental Health Administration, Center for Disease Control, *Ten-State Nutrition Survey, 1968–1970,* DHEW Publication No. (HSM) 72–8130–72–8134 (Washington, D.C.: U.S. Government Printing Office, 1972).

(23) George Owen et al., "A Study of Nutritional Status of Preschool Children in the United States, 1968–1970," *Pediatrics* (Suppl.) 53 (1974).

(24) U.S. Department of Health, Education, and Welfare, Public Health Service and Mental Health Administration, *First Health and Nutrition Examination Survey, United States, 1971–1972,* DHEW Publication No. (HRA) 74–121901 (Washington, D.C.: U.S. Government Printing Office, 1974).

(25) Joseph C. Edozien, B. R. Switzer, R. B. Bryan, *Medical Evaluation of the Special Supplemental Food Program for Women, Infants and Children (WIC),* Report to the Congress, 1976.

(26) Eileen Kennedy "Evaluation of the Special Supplemental Food Program for women, Infants and Children on Prenatal Patients in Massachusetts" (Doctoral thesis, Harvard School of Public Health, 1979).

(27) U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, "CDC Analysis of Nutritional Indices for Selected WIC Participants," December 1977.

(28) Food and Nutrition Board, *Recommended Dietary Allowances,* Ninth Edition.

(29) U.S. Department of Agriculture, Food and Nutrition Service, Supplemental Food Programs Division, *WIC Participant Profile Survey* (Washington, D.C.: Food and Nutrition Service, USDA, 1979).

(30) Peter M. Ranum and R. J. Loewe, "Iron Enrichment of Cereals," *The Bakers Digest* (June 1978): 14–20.

(31) B. N. Harrison, G. W. Pla, G. A. Clark and J. C. Fritz, "Selection of Iron Sources for Cereal Enrichment," *Cereal Chemistry* 53 (1976): 78–84.

(32) Ranum and Loewe, "Iron Enrichment of Cereals."

(33) Life Sciences Research Office, Federation of American Societies for Experimental Biology, *Evaluation of the Health Aspects of Sucrose as a Food Ingredient,* FDA Contract No. FDA 223–75–2004 (Bethesda, Md.: Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976).

(34) "Symposium: Can Disease of Overconsumption Be Prevented by Dietary Changes? A Critique of the Evidence", sponsored by the American Society for Clinical Nutrition, W. E. Connor and E. H. Ahrens, Jr., Cochairmen (Bethesda, Md., 1979).

(35) U.S. Department of Health, Education, and Welfare, Public Health Service, Office of the Assistant Secretary for Health and Surgeon General, *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention,* DHEW (PHS) Publication No. 79–55071 (Washington, D.C.: U.S. Government Printing Office, 1979).

(36) American Academy Pediatrics, 1979). Foman, Younozai and Thomas J. Nutr. 89, 345 (1966).

(37) Goodhart, Robert S. and Maurice E. Shils (eds.), *Modern Nutrition in Health and Disease,* fifth edition (Philadelphia: Lea & Febiger, 1973).

(39) Thomas J. Sobotka, "Update on Studies of the Relationship Between Hyperkinesis in Children and Food Additives," *FDA By-Lines* (in press).

(40) Thomas J. Sobotka, Division of Toxicology, Food and Drug Administration, Washington, D.C., personal communication, September 1979.

It is proposed to revise 7 CFR 246.8 to read as follows:

§ 246.8 Supplemental foods.

(a) *General.* This section prescribes the requirements for providing supplemental foods to participants.

(b) *State agency responsibilities.* State agencies shall:

(1) Identify foods which are acceptable for use under the Program in accordance with the requirements of this section and provide a list of acceptable foods and maximum monthly quantities to local agencies, State auditors, and Department auditors; and

(2) Ensure that local agencies: (i) make available at least one food from each group in each food package listed in paragraph (c) of this section. However, this does not mean that the local agency must provide each participant with a food from each food group.

(ii) Make available to participants the supplemental foods, as authorized in paragraph (c) of this section; and

(iii) Designate a competent professional authority to prescribe types of supplemental foods in quantities appropriate for the participant, taking into consideration, at each certification, the participant's age and dietary needs. In the case of breast fed infants, if supplemental feedings of infant formula are necessary or desired, infants should receive appropriate quantities of infant formula. The amount of supplemental foods shall not exceed the maximum quantities specified in this section:

(c) *Food packages.* There are seven food packages available under the Program which may be provided to participants. The authorized supplemental foods shall be prescribed from food packages according to the category and nutritional need of the participant. The food packages are as follows:

Note.—The metric units given are mathematical conversions. If packaging practices change, the authorized food quantities will be revised accordingly.

(1) *Food Package I—Infants 0 to 2–4 months.* (i) Iron-fortified formula intended for use by infants, which is a complete formula not requiring the addition of any ingredients other than water prior to being served in a liquid state, and which contains at least 10 miligrams of iron per liter of formula at standard dilution which supplies 67 kilocalories per 100 mililiters, i.e., approximately 20 kilocalories per fluid once of formula at standard dilution. Concentrated liquid or powdered formula shall be provided, except that ready-to/feed formula may be authorized when the competent professional authority determines and documents that there is an unsanitary or restricted water supply, that there is poor refrigeration or that the person who is caring for an infant may have difficulty in correctly diluting concentrated liquid or powdered formula.

(ii) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Infant formula:	
Concentrated liquid formula—	403 fluid oz. (11.9 liters).
Addition*	52 fluid oz. (1.5 liters).
or	
Powdered formula	May be substituted at the rate of 8 lb (3.6 kg) per 403 fluid oz. (11.9 liters) of concentrated liquid formula.
Addition*	1 lb. (.4 kg).
or	
Ready-to-feed formula	May be substituted at the rate of 26 fluid oz. (.8 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
Addition*	104 fluid oz. (3.1 liters).

*Additional formula may be issued on an individual basis provided the need is demonstrated and documented in the individual's certification file by a physician.

(2) *Food Package II—Infants 2–4 to 6 months.* (i) Formula as specified in paragraph (c)(1)(i).

(ii) Infant cereal which contains a minimum of 45 milligrams of iron per 100 grams of dry cereal.

(iii) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Infant formula:	
Concentrated liquid formula—	403 fluid oz. (11.9 liters).
Addition*	52 fluid oz. (1.5 liters).
or	
Powdered formula	May be substitution at the rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 liters) of concentrated liquid formula.
Addition*	1 lb. (.4 kg).
or	
Ready-to-feed formula	May be substituted at the rate of 26 fluid oz. (.8 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
Addition*	104 fluid oz. (3.1 liters).
Infant cereal	24 oz. dry (.7 kg).

*Additional formula may be issued on an individual basis provided the need is demonstrated and documented in the individual's certification file by a physician.

(3) *Food Package III—Infants 6 to 12 months.* (i) Infant formula as specified in paragraph (c)(1)(i) *Substitutes.* The following types of milk may be substituted for all or part of the infant formula: Pasteurized fluid whole milk which is unflavored and which contains 400 International Units of vitamin D per quart (.9 liter); or evaporated whole milk which contains 400 International units of vitamin D per reconstituted quart (.9 liter), or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter). However, the participant's parent or guardian shall be informed that the substitution will result in a reduction of the iron content in the infant food package. Additionally, if the physician determines and documents the need for a low calorie infant formula, infants may receive an iron-fortified infant formula intended for use by infants which is a complete nutritional beverage not requiring the addition of any ingredients other than water prior to being served in a liquid state, which contains at least 10 milligrams of iron per liter of formula at standard dilution and which supplies 54 kilocalories per 100 milliliters, i.e., approximately 16 kilocalories per fluid ounce at standard dilution. Concentrated liquid or powdered formula shall be provided, except that ready-to-feed formula may be authorized when the competent professional authority determines and documents that there is an unsanitary or restricted water supply, that there is poor refrigeration or that the person who is caring for an infant may have difficulty in correctly diluting concentrated liquid or powdered formula.

(ii) Infant cereal which contains a minimum of 45 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice. Infant juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters may be authorized provided the need is documented by a competent professional authority.

(iv) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Infant formula:	
Concentrated liquid formula—	403 fluid oz. (11.9 liters).
Addition*	52 fluid oz. (1.5 liters).
or	
Powdered formula	May be substituted at the rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 liters) of concentrated liquid formula.
Addition*	1 lb. (.4 kg).
or	
Ready-to-feed formula	May be substituted at the rate of 26 fluid oz. (.8 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
Addition*	104 fluid oz. (3 liters).
or	
Fluid whole milk	92 fluid oz. (2.7 liters).

or	
Frozen concentrated juice	May be substituted for formula at the rate of 1 qt. (.9 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
or	
Evaporated whole milk	May be substituted for formula at the rate of 13 fluid oz. (.4 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
or	
Dry whole milk	May be substituted for formula at the rate of 1 lb. (.4 kg) per 39 fluid oz. (1.2 liters) of concentrated liquid formula.
Infant cereal	24 oz., dry (.7 kg).
Juice:	
Single strength adult juice	May be substituted as long as the reconstituted volume is no greater than the amount authorized for single strength juice.
or	
Infant juice	May be substituted at the rate of 63 fluid oz. (1.9 liters) of infant juice per 92 fluid oz. (2.7 liters) of single strength adult juice.

* Additional formula may be issued on an individual basis provided the need is demonstrated and documented in the individual's certification file by a physician. The additional formula does not apply to low-calorie formula, fluid whole milk, evaporated whole milk, or dry whole milk.

(4) *Food Package IV—Children 1 to 5 years.* (i) Pasteurized fluid whole milk which is flavored or unflavored and which contains 400 International Units of vitamin D per quart (.9 liter); or pasteurized fluid skim or lowfat milk which is flavored or unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart or evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, Natural cheddar, Swiss, Brick, Edam, Gouda, Meunster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Cereal (hot or cold) which contains a minimum of 15 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce), except that for participants who at certification exhibit signs of iron deficiency the iron content of the cereal shall not be less than 28 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs of dried egg mix.

(v) Peanut butter or mature dried beans or peas, includig but not limited to lentils, black, navy, kidney, garbonzo, soy, pinto, and mung beans, crowder, cow, split and black-eyed peas.

(vi) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk:	
Fluid whole milk	24 qt. (22.7 liters).
or	
Fluid skim or lowfat milk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Evaporated whole milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Evaporated skimmed milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
or	
Nonfat or lowfat dry milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 5 qt. (4.7 liters) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
Eggs:	
Eggs	2 doz.
or	
Dried egg mix	May be substituted at the rate of 1.5 lb. (.7 kg) egg mix per 2 doz. fresh eggs.
Cereals (hot or cold)	36 oz., dry (1 kg).
Juice:	
Single strength juice	276 fluid ounces (8.2 liters).
or	
Frozen concentrated juice	May be substituted as long as the reconstituted volume is no greater than the amount authorized for single strength juice
Legumes:	
Dry beans or peas	1 lb. (.4 kg).
or	
Peanut butter	18 ounces (.5 kg).

(5) *Food Package V—Children with Special Dietary Needs.* Children with special dietary needs may receive the following supplemental foods if the physician determines and documents that such a child's condition precludes the use of the supplemental foods specified in paragraph (c)(4) of this section. (i) Infant formula as specified in paragraph (c)(1)(i) of this section. *Substitutes.* If the physician determines and documents the need for a low calorie infant formula children may receive an iron fortified infant formula intended for use by infants which is a complete nutritional beverage not requiring the addition of any ingredients other than water prior to being served in a liquid state, which contains at least 10 milligrams of iron per liter of formula at standard dilution and which supplies 54 kilocalories per 100 milliliters, i.e., approximately 16 kilocalories per fluid ounce at standard dilution. Concentrated liquid or powdered formula shall be provided, except that ready-to-feed formula may be authorized when the competent professional authority determines and documents that there is an unsanitary or restricted water supply, that there is poor refrigeration or that the person who is caring for an infant may have difficulty in correctly diluting concentrated liquid or powdered formula.

(ii) Cereal (hot or cold) which contains a minimum of 15 milligrams or iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce), except that for participants who at certification exhibit signs of iron deficiency the iron content of the cereal shall not be less than 28 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Infant formula:	
Concentrated liquid formula	403 fluid oz. (11.9 liters).
Addition*	52 fluid oz. (1.5 liters).
or	
Powdered formula	May be substituted at a rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 liters) of concentrated liquid formula.
Addition*	1 lb. (.4 kg).
or	
Ready-to-feed formula	May be substituted at the rate of 26 fluid oz. (.8 liter) per 13 fluid oz. (.4 liter) of concentrated liquid formula.
Addition*	104 fluid oz. (3.1 liters).
Cereal (hot or cold)	36 oz., dry (1 kg).
Juice:	
Single strength juice	138 fluid oz. (4.1 liters).

Frozen concentrated juice	May be substituted as long as the reconstituted volume is no greater than the amount authorized for single strength juice.

*Additional formula may be issued on an individual basis provided the need is demonstrated and documented in the individual's certification file by a physician. The additional formula does not apply to low-calorie formula.

(6) *Food Package VI—Pregnant and Breastfeeding Women.* (i) Pasteurized fluid whole milk which is flavored or unflavored and which contains 400 International Units of vitamin D per quart (.9 liters); or pasteurized fluid skim or lowfat milk which is flavored or unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, Natural Cheddar, Swiss, Brick, Edam, Gouda, Meunster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Adult cereal (hot or cold) which contains a minimum of 15 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce), except that for participants who at certification exhibit signs of iron deficiencies the iron content of the cereal shall not be less than 28 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs or dried egg mix.

(v) Peanut butter or mature dried beans of peas, including but not limited to lentils, black, navy, kidney, garbonzo, soy, pinto and mung beans, crowder, cow, split and black-eyed peas.

(vi) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk	
Fluid whole milk	28 qt. (26.5 liters).
Fluid skim or lowfat milk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Evaporated whole milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
Evaporated skimmed milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
or	
Nonfat or lowfat dry milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 5 qt. (4.7 liters) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
Eggs	
Eggs	2 doz.
Dried egg mix	May be substituted at the rate of 1.5 lb. (.7 kg) egg mix per 2 doz. fresh eggs.
Cereal (hot or cold)	36 oz., dry (1 kg).
Juice:	
Single strength juice	276 fluid oz. (8.2 liters)
Frozen, concentrated juice	May be substituted as long as the reconstituted volume is no greater than the amount authorized for single strength juices.
Legumes:	
Dry beans and peas	1 lb. (.4 kg).
Peanut butter	18 ounces (.5 kg)

(7) *Food Package VII—Postpartum Women.* (i) Pasteurized fluid whole milk which is flavored or unflavored and which contains 400 International Units of vitamin D per quart (.9 liter); or pasteurized fluid skim or lowfat milk which is flavored or unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, Natural cheddar, Swiss, Brick, Edam, Gouda, Meunster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Adult cereal (hot or cold) which contains a minumum of 15 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per 1 oz.), except for participants who at certification exhibit signs of iron deficiency the iron content of the cereal shall not be less than 28 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs or dried egg mix.

(v) The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk	
Fluid whole milk	24 qt. (22.7 liters)
or	
Fluid skim or lowfat milk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
Evaporated whole milk	May be substituted for fluid whole milk at the rate of 13 fluid ounces (.4 liter) per qt (.9 liter) of fluid whole milk.
Evaporated skimmed milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
Nonfat or lowfat dry milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 5 qt. (4.7 liters) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg) per 3 qt. (2.8 liters) of fluid whole milk.
Eggs	
Eggs	2 doz.
Dried egg mix	May be substituted at the rate of 1.5 lb. (.7 kg) egg mix per 2 doz. fresh eggs.
Cereal (hot or cold)	36 oz., dry (1 kg).
Juice:	
Single strength juice	184 fluid ounces (5.4 liters).

Food	Quantity
Frozen concentrated juice.....	May be substituted as long as the reconstituted volume is no greater than the amount authorized for single strength juice.

(d) *Use of Commodity Foods.* (1) At the request of a State agency, the Department shall purchase commodity foods for the State agency using funds allocated to the State agency. The commodity foods purchased and made available to the State agency shall be equivalent to the foods specified in paragraph (c) of this section.

(2) The State agency shall:

(i) Distribute the commodity foods to the local agency.

(ii) Ensure satisfactory storage conditions for the commodity foods, including documentation of proper insurance.

(iii) Ensure that the local agency has proper storage facilities for the commodity foods.

(e) *Substitute foods.* (1) The State agency may submit to FNS a plan for substitution of foods acceptable for use in the Program to allow for different cultural eating patterns. The plan shall include the State's agency's justification for the proposed substitution, including a specific explanation of the cultural eating pattern which requires the proposed substitution and other information necessary for FNS to evaluate the plan as specified in paragraph (e)(2) of this section.

(2) FNS shall evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria:

(i) *Nutritional equivalence.* Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace.

(ii) *Availability.* The proposed substitute must be widely available to participants in the areas where the substitute is intended to be used.

(iii) *Cost.* The cost of the substitute must be equivalent to or less than the cost of the food it is intended to replace.

(3) FNS shall approve the State plan for substitution of foods for different cultural eating patterns based on the evaluation criteria specified in paragraph (2) above and the State agency's justification for the substitution. The State agency shall use substitute foods only after receiving the written approval of FNS.

(Child Nutrition Amendments of 1978, Pub. L. 95-627, 92 Stat. 3603 *et seq.*)

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations," and has been classified "significant." An Approved Draft Impact Analysis is available from Jane W. McNeil, Acting Director, Supplemental Food Program Division, FNS, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-8206.

Dated: November 27, 1979.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

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